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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,382	01/25/2001	Ian Richard Anselm Peak	8795-24 U1	6450
570 7590 11/26/2008 PANITCH SCHWARZE BELISARIO & NADEL LLP ONE COMMERCE SQUARE 2005 MARKET STREET, SUITE 2200 PHILADELPHIA, PA 19103				
EXAMINER				
FORD, VANESSA L				
ART UNIT		PAPER NUMBER		
1645				
MAIL DATE		DELIVERY MODE		
11/26/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/771,382

Applicant(s)

PEAK ET AL.

Examiner

VANESSA L. FORD

Art Unit

1645

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33, 34, 49-52, 54, 55 and 57-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 33, 34, 49-52, 54, 55 and 57-60 is/are allowed.
- 6) ☒ Claim(s) 61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notices of Informal Patent Application
- 6) ☐ Other: _____

FINAL ACTION

1. This action is responsive to Applicant's amendment and response filed August 8, 2008. Claims 54, 57, 59 and 60 have been amended. Claims 1-32, 35-48, 53 and 56 have been canceled. Claim 61 has been added.

Claims under examination are 33-34, 49-52, 54-55 and 57-61 are under examination.

Rejections Withdrawn

2. In view of Applicant's amendment and response the following rejections:

a) rejection of claims 54-55 and 57-60 under 35 U.S.C. 112, first paragraph (scope of enablement), pages 3-10, paragraph 3 of the previous Office action.

b) rejection of claims 54-55 and 57-60 under 35 U.S.C. 112, first paragraph (written description) pages 10-17 paragraph 4 of the previous Office action.

New Grounds of Rejection Necessitated by Applicant's Amendment

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claim 61 is rejected under 35 U.S.C. 102(a) as anticipated by Masignani et al (*WO 99/36544 published July 22, 1999*).

Claim 61 is directed to an isolated protein having at least 90% sequence identity to SEQ ID NO:23 or SEQ ID No.35, wherein the isolated protein is immunogenic.

Masignani et al teach proteins from *Neisseria meningitidis* and immunogenic compositions as well as pharmaceutical compositions containing the polypeptide (see the Abstract and pages 29-30). Masignani et al teach that fusion protein that can provide an alternative to direct protein expression (page 20). Masignani et al teach a *N. meningitidis* protein ORF40-1 protein (SEQ ID NO:4) that has the amino acid sequence that is 98.1% identity to SEQ ID NO:23. See the sequence alignment below:

```
Query Match          98.1%; Score 2550.5; DB 2; Length 591;
Best Local Similarity 86.6%; Pred. No. 4.1e-150;
Matches 512; Conservative 0; Mismatches 0; Indels 79; Gaps
1;

Qy      1 MNKIYRIIWNLSALNAWVVVSELTRNHTKRASATVKTAVLATLLFATVQASANNE----- 54
      ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      1 MNKIYRIIWNLSALNAWVVVSELTRNHTKRASATVKTAVLATLLFATVQASANNEEQEEDL 60

Qy      55 ----- 54

Db      61 YLDPVQRTVAVLIVNSDKEGTGEKEKVEENS DWAVYFNEKGVLTA REITLKAGDNLKIKQ
120

Qy      55 -----TDLTSVGTEKLSFSANGNKVNI TSDTKGLNFAKETAGTNGD TTVHNL
101
      ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      121 NGTNFTYSLKDLTDLTSVGTEKLSFSANGNKVNI TSDTKGLNFAKETAGTNGD TTVHNL
180

Qy      102 GIGSTLTDTLNLTGATTNVTNDNVTDDEKKRAASVKVDVLNAGWNIGVKPGTTASDNVDF
161
      ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      181 GIGSTLTDTLNLTGATTNVTNDNVTDDEKKRAASVKVDVLNAGWNIGVKPGTTASDNVDF
240
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Qy      162 VRTYDTVEFLSADTKTTTVNVESKDNGKKTEVKIGAKTSVIKEKDGLVTKGDKGKENGSS
221      |
Db      241 VRTYDTVEFLSADTKTTTVNVESKDNGKKTEVKIGAKTSVIKEKDGLVTKGDKGKENGSS
300      |

Qy      222 TDEGEGLVTAKEVIDAVNKAGWRMKT TTANGQTGQADKFETVTSGTNVTFASGKGTATV
281      |
Db      301 TDEGEGLVTAKEVIDAVNKAGWRMKT TTANGQTGQADKFETVTSGTNVTFASGKGTATV
360      |

Qy      282 SKDDQGNITVMYDVNVGDALNVNQLQNSGWNLDSKAVAGSSGKVISGNVSPSKGKMDTV
341      |
Db      361 SKDDQGNITVMYDVNVGDALNVNQLQNSGWNLDSKAVAGSSGKVISGNVSPSKGKMDTV
420      |

Qy      342 NINAGNNIEITRNGKNIDIATSMTPQFSSVSLGAGADAPTLSDGDALNVGSKKDNKPKVR
401      |
Db      421 NINAGNNIEITRNGKNIDIATSMTPQFSSVSLGAGADAPTLSDGDALNVGSKKDNKPKVR
480      |

Qy      402 ITNVAPGVKEGDVTNVAQLKGVAQNLNNRIDNVGDGNARAGIAQAIATAGLVQAYLPGKSM
461      |
Db      481 ITNVAPGVKEGDVTNVAQLKGVAQNLNNRIDNVGDGNARAGIAQAIATAGLVQAYLPGKSM
540      |

Qy      462 MAIGGGTYRGEAGYAIGYSSISDGGNWI IKG TASGNSRGHFGASASVGYQW 512
541      |
Db      541 MAIGGGTYRGEAGYAIGYSSISDGGNWI IKG TASGNSRGHFGASASVGYQW 591

```

Masignani et al teach a *N. meningitidis* protein ORF40-1 protein (SEQ ID NO:4)

that has the amino acid sequence that is 99.3% identity to SEQ ID NO:35. See the sequence alignment below:

```

Query Match      99.3%; Score 2333; DB 2; Length 591;
Best Local Similarity 100.0%; Pred. No. 5.5e-140;
Matches 458; Conservative 0; Mismatches 0; Indels 0; Gaps
0;

Qy      4 TDLTSVSGTEKLSFSANGNKVNITSDTKGLNFAKETAGTNGD TTVHLNGIGSTLTDTLLNT 63
Db      134 TDLTSVSGTEKLSFSANGNKVNITSDTKGLNFAKETAGTNGD TTVHLNGIGSTLTDTLLNT
193

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```
Qy      64  GATTNVTNDNVTDDKKRAASVKDVLNAGWNIGVKPGTTASDNVDFVRTYDTVEFLSAD
123
      |||
Db      194  GATTNVTNDNVTDDKKRAASVKDVLNAGWNIGVKPGTTASDNVDFVRTYDTVEFLSAD
253
      |||
Qy      124  TKTTTVNVESKDNGKKTEVKIGAKTSVIKEKDGLVTKDKKGENGSSTDEGEGLVTAKEV
183
      |||
Db      254  TKTTTVNVESKDNGKKTEVKIGAKTSVIKEKDGLVTKDKKGENGSSTDEGEGLVTAKEV
313
      |||
Qy      184  IDAVNKAGWRMKT TT TANGQTGQADKFETVTS GTNVT FASGKGT TATVSKDDQGNITVMYD
243
      |||
Db      314  IDAVNKAGWRMKT TT TANGQTGQADKFETVTS GTNVT FASGKGT TATVSKDDQGNITVMYD
373
      |||
Qy      244  VNVGDALNVNQLQNSGWNLDSKAVAGSSGKVISGNVSPSKGKMDETVNI NAGNNIEITRN
303
      |||
Db      374  VNVGDALNVNQLQNSGWNLDSKAVAGSSGKVISGNVSPSKGKMDETVNI NAGNNIEITRN
433
      |||
Qy      304  GKNIDIATSMTPQFSSVSLGAGADAP T LSV DGDALNVGSKKDNKPVRITNVAPGVKEGDV
363
      |||
Db      434  GKNIDIATSMTPQFSSVSLGAGADAP T LSV DGDALNVGSKKDNKPVRITNVAPGVKEGDV
493
      |||
Qy      364  TNVAQLKGVAQN LNNRIDNV DGNARAGIAQA IATAGLVQAYLPGKSMM AIGGGTYRGEAG
423
      |||
Db      494  TNVAQLKGVAQN LNNRIDNV DGNARAGIAQA IATAGLVQAYLPGKSMM AIGGGTYRGEAG
553
      |||
Qy      424  YAIGYSSISDGGNWI IKG TASGNSRGHFGASASVGYQW 461
      |||
Db      554  YAIGYSSISDGGNWI IKG TASGNSRGHFGASASVGYQW 591
```

The protein and pharmaceutical compositions of Masignani et al appear to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's protein and pharmaceutical compositions with the protein and

pharmaceutical compositions of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein and pharmaceutical compositions of the prior art does not possess the same material structural and functional characteristics of the claimed protein and pharmaceutical compositions). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

4. Claim 61 is rejected under 35 U.S.C. 102(a) as anticipated by Peak et al (*WO 99/31132 published June 24, 1999*).

Claim 61 is directed to an isolated protein having at least 90% sequence identity to SEQ ID NO:23 or SEQ ID No.35, wherein the isolated protein is immunogenic.

Peak et al teach proteins from *Neisseria meningitidis* and pharmaceutical compositions containing the polypeptide (see the Abstract and pages 34-40). Peak et al teach a *N. meningitidis* protein (SEQ ID NO:21) that has the amino acid sequence that is 98.1% identity to SEQ ID NO:23.

```
Query Match          98.1%; Score 2550.5; DB 2; Length 591;
Best Local Similarity 86.6%; Pred. No. 4.1e-150;
Matches 512; Conservative 0; Mismatches 0; Indels 79; Gaps
1;

Qy      1 MNKIYRIIWNNSALNANWVVSSELTRNHTKRASATVKTAVLATLLFATVQASANNE----- 54
        |||||||
Db      1 MNKIYRIIWNNSALNANWVVSSELTRNHTKRASATVKTAVLATLLFATVQASANNEEQEEDL 60

Qy      55 ----- 54

Db      61 YLDPVQRTVAVLIVNSDKGTGEKEKVEENSDWAVYFNEKGVLTAREITLKAGDNLKIKQ
120
```

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```

Qy      55 -----TDLTSVGTEKLSFSANGNKVNITSDTKGLNFAKETAGTNGDTTVHLN
101
      |||
Db      121 NGNTFTYSLKKDLTDLTSVGTEKLSFSANGNKVNITSDTKGLNFAKETAGTNGDTTVHLN
180
Qy      102 GIGSTLTDTLLNTGATTNVTNDNVTDDEKKRAASVKDVLNAGWNIGVKPGTTASDNVDF
161
      |||
Db      181 GIGSTLTDTLLNTGATTNVTNDNVTDDEKKRAASVKDVLNAGWNIGVKPGTTASDNVDF
240
Qy      162 VRTYDTVEFLSADTKTTTVNVEKDNKGKTEVKIGAKTSVIKEKDGKLVTKDKKENGSS
221
      |||
Db      241 VRTYDTVEFLSADTKTTTVNVEKDNKGKTEVKIGAKTSVIKEKDGKLVTKDKKENGSS
300
Qy      222 TDEGEGLVTAKEVIDAVNKAGWRMKT TTANGQTGQADKFETVTSGTNVTFASGKGTATV
281
      |||
Db      301 TDEGEGLVTAKEVIDAVNKAGWRMKT TTANGQTGQADKFETVTSGTNVTFASGKGTATV
360
Qy      282 SKDDQGNITVMYDVNVGDALNVNQLQNSGWNLDSKAVAGSSGKVISGNVSPSKGMDETV
341
      |||
Db      361 SKDDQGNITVMYDVNVGDALNVNQLQNSGWNLDSKAVAGSSGKVISGNVSPSKGMDETV
420
Qy      342 NINAGNNIEITRNGKNIDIATSMTPQFSSVSLGAGADAPTLSDGDALNVGSKKDNKPVR
401
      |||
Db      421 NINAGNNIEITRNGKNIDIATSMTPQFSSVSLGAGADAPTLSDGDALNVGSKKDNKPVR
480
Qy      402 ITNVAPGVKEGDVTNVAQLKGVAQNLNNRIDNVGDGNARAGIAQAIATAGLVQAYLPGKSM
461
      |||
Db      481 ITNVAPGVKEGDVTNVAQLKGVAQNLNNRIDNVGDGNARAGIAQAIATAGLVQAYLPGKSM
540
Qy      462 MAIGGGTYRGEAGYAIGYSSISDGGNWI IKG TASGNSRGHFGASASVGYQW 512
      |||
Db      541 MAIGGGTYRGEAGYAIGYSSISDGGNWI IKG TASGNSRGHFGASASVGYQW 591

```

Peak et al teach a *N. meningitidis* protein (SEQ ID NO:21) that has the amino acid sequence that is 99.3% identity to SEQ ID NO:35.

Art Unit: 1645

Query Match 99.3%; Score 2333; DB 2; Length 591;
 Best Local Similarity 100.0%; Pred. No. 5.5e-140;
 Matches 458; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 4 TDLTSVGTEKLSFSANGNKVNITSDTKGLNFAKETAGTNGDTTVHLNIGIGSTLTDTLLNT 63
 |||
 Db 134 TDLTSVGTEKLSFSANGNKVNITSDTKGLNFAKETAGTNGDTTVHLNIGIGSTLTDTLLNT
 193

Qy 64 GATTNVTNDNVTDDEKKRAASVKDVLNAGWNIGVKPGTTASDNVDFVRTYDTEVFLSAD
 123
 |||
 Db 194 GATTNVTNDNVTDDEKKRAASVKDVLNAGWNIGVKPGTTASDNVDFVRTYDTEVFLSAD
 253

Qy 124 TKTTTNNVESKDNGKKTEVKIGAKTSVIEKDGKLVGTGKDKGENGSSTDEGEGLVTAKEV
 183
 |||
 Db 254 TKTTTNNVESKDNGKKTEVKIGAKTSVIEKDGKLVGTGKDKGENGSSTDEGEGLVTAKEV
 313

Qy 184 IDAVNKAGWRMKTITANGQTGQADKFETVTSNTVTFASGKGTATVSKDDQGNITVMYD
 243
 |||
 Db 314 IDAVNKAGWRMKTITANGQTGQADKFETVTSNTVTFASGKGTATVSKDDQGNITVMYD
 373

Qy 244 VNVGDALNVNQLQNSGWNLDKAVAGSSGKVISGNVSPSKGKMDETVNIAGNNIEITRN
 303
 |||
 Db 374 VNVGDALNVNQLQNSGWNLDKAVAGSSGKVISGNVSPSKGKMDETVNIAGNNIEITRN
 433

Qy 304 GKNIDIATSMTPQFSSVSLGAGADAPTLSDVDGALNVGSKKDNKPVIRITNVAPGVKEGDV
 363
 |||
 Db 434 GKNIDIATSMTPQFSSVSLGAGADAPTLSDVDGALNVGSKKDNKPVIRITNVAPGVKEGDV
 493

Qy 364 TNVAQLKGVAQNLNRRIDNVGDNARAGIAQAIAATAGLVQAYLPGKSMAIGGGTYRGEAG
 423
 |||
 Db 494 TNVAQLKGVAQNLNRRIDNVGDNARAGIAQAIAATAGLVQAYLPGKSMAIGGGTYRGEAG
 553

Qy 424 YAIGYSSISDGGNWIIGKTASGNSRGHFGASASVGYQW 461
 |||
 Db 554 YAIGYSSISDGGNWIIGKTASGNSRGHFGASASVGYQW 591

The protein and pharmaceutical compositions of Peak et al appear to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's protein and pharmaceutical compositions with the protein and pharmaceutical compositions of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein and pharmaceutical compositions of the prior art does not possess the same material structural and functional characteristics of the claimed protein and pharmaceutical compositions). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

5. Claim 61 is rejected under 35 U.S.C. 102(e) as anticipated by Peak et al (*U. S. Patent No.6,197,312 B1 published March 2001, filed August 19, 1999*).

Claim 61 is directed to an isolated protein having at least 90% sequence identity to SEQ ID NO:23 or SEQ ID No.35, wherein the isolated protein is immunogenic.

Peak et al teach proteins from *Neisseria meningitidis* and pharmaceutical compositions containing the polypeptide (see the Abstract and columns 16-18). Peak et al teach a *N. meningitidis* protein (SEQ ID NO:21) that has the amino acid sequence that is 98.1% identity to SEQ ID NO:23. The protein and pharmaceutical compositions of Peak et al appear to be the same as the claimed invention.

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```

Qy      462 MAIGGGTYRGEAGYAIGYSSISDGGNWIKGTASGNSRGHFGASASVGYQW 512
          ||||||||||||||||||||||||||||||||||||||||||||||||
Db      541 MAIGGGTYRGEAGYAIGYSSISDGGNWIKGTASGNSRGHFGASASVGYQW 591

```

Peak et al teach a *N. meningitidis* protein (SEQ ID NO:21) that has the amino acid sequence that is 99.3% identity to SEQ ID NO:35.

```

Query Match          99.3%; Score 2333; DB 2; Length 591;
  Best Local Similarity 100.0%; Pred. No. 3.7e-181;
  Matches 458; Conservative 0; Mismatches 0; Indels 0; Gaps
0;

Qy      4 TDLTSVGTEKLSFSANGNKVNITSDTKGLNFAKETAGTNGDTTVHLNGIGSTLTDLLNT 63
          ||||||||||||||||||||||||||||||||||||||||||||||||
Db      134 TDLTSVGTEKLSFSANGNKVNITSDTKGLNFAKETAGTNGDTTVHLNGIGSTLTDLLNT
193

Qy      64 GATTNVTNDNVTDDEKKRAASVKDVLNAGWNKIGVKPGTTASDNVDFVRTYDTEVFLSAD
123
          ||||||||||||||||||||||||||||||||||||||||||||||||
Db      194 GATTNVTNDNVTDDEKKRAASVKDVLNAGWNKIGVKPGTTASDNVDFVRTYDTEVFLSAD
253

Qy      124 TKTTTVNVESKDNGKKTEVKIGAKTSVIKEKDGLVTGKDKGENSSSTDEGEGLVTAKEV
183
          ||||||||||||||||||||||||||||||||||||||||||||||||
Db      254 TKTTTVNVESKDNGKKTEVKIGAKTSVIKEKDGLVTGKDKGENSSSTDEGEGLVTAKEV
313

Qy      184 IDAVNKAGWRMKT TTTANGQTGQADKFETVTSNTVFASGKGTTATVSKDDQGNITVMYD
243
          ||||||||||||||||||||||||||||||||||||||||||||||||
Db      314 IDAVNKAGWRMKT TTTANGQTGQADKFETVTSNTVFASGKGTTATVSKDDQGNITVMYD
373

Qy      244 VNVGDALNVNQLQNSGWNLDSKAVAGSSGKVISGNVSPSKGKMDETVNIAGNNIEITRN
303
          ||||||||||||||||||||||||||||||||||||||||||||||||
Db      374 VNVGDALNVNQLQNSGWNLDSKAVAGSSGKVISGNVSPSKGKMDETVNIAGNNIEITRN
433

Qy      304 GKNIDIATSMTPQFSSVSLGAGADAPTLSDVDALNVGSKKDNKPVIRITNAPGVKEGDV
363
          ||||||||||||||||||||||||||||||||||||||||||||||||
Db      434 GKNIDIATSMTPQFSSVSLGAGADAPTLSDVDALNVGSKKDNKPVIRITNAPGVKEGDV
493

Qy      364 TNVAQLKGVAQN LNNRIDNV DGNARAGIAQAIATAGLVQAYLPKGSMMMAIGGGTYRGEAG
423
          ||||||||||||||||||||||||||||||||||||||||||||||||

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Db      494  TNVAQLKGVAQNLNRRIDNVDGNARAGIAQAIAATAGLVQAYLPGKSMMAIGGGTYRGEAG
553
Qy      424  YAIGYSSISDGGNWIKGTASGNSRGHFGASASVGYQW 461
          |||
Db      554  YAIGYSSISDGGNWIKGTASGNSRGHFGASASVGYQW 591
```

Since the Office does not have the facilities for examining and comparing applicant's protein and pharmaceutical compositions with the protein and pharmaceutical compositions of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein and pharmaceutical compositions of the prior art does not possess the same material structural and functional characteristics of the claimed protein and pharmaceutical compositions). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Status of Claims

7. Claims 33-34, 49-52, 54-55 and 57-60 are free of the cited art and are allowable.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanessa L. Ford whose telephone number is (571) 272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0856 the fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vanessa L. Ford/
Patent Examiner, Art Unit 1645
November 20, 2008

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645